



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/938,406

08/21/2001

George H. Lowell

484112.408D1

1965

500

7590

01/30/2008

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

01/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/938,406	Applicant(s) LOWELL ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 21-23, 26-28, 30 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-23, 26-28, 30, and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 19, 21-23, 26-28, 30, and 35 are pending and under consideration.
2. In the prior action, claims 19 and 21-35 were pending and rejected.
3. In the Response of November 14, 2007, the Applicant amended claims 19 and 27; and cancelled claims 24, 25, 29, and 31-34.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **(Prior Rejection-Maintained)** Claims 19, 21-26, and 28-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of the 292 patent or of Lowell (hereinafter, "the Lowell article," Science 240: 800-802), in view of VanCott (J Immunol Methods 183: 103-17), and further in view WO 95/11700. Claims 24, 25, 29, and 31-34 have been cancelled from the application. The rejection is therefore withdrawn from these claims.

The Applicant traverses the rejection of the pending claims on two grounds. First, the Applicant asserts that the cited references do not render obvious the claimed invention because the cited references do not teach the formulation of gp160 for mucosal administration. This argument is not found persuasive. While the references do not specifically teach that the gp160 compositions are formulated for mucosal administration, the teachings do suggest the

Art Unit: 1648

combination of gp160 with the proteosomes and nanoemulsions as claimed. Thus, there is no structural difference between the claimed invention and that suggested by the prior art.

Moreover, the teachings in WO 95/11700 indicate that the proteosomes confer mucosal immunogenicity onto attached antigens. Page 21, lines 24-27. In view of these teachings, and the lack of any structural difference between the claimed invention and the composition suggested by the prior art, the Applicant's first argument is not found persuasive.

The Applicant also argues that, even if *prima facie* case of obviousness has been made, the rejection should be withdrawn on the basis of the unexpected benefits of the use of the truncated gp120 to induce the production of neutralizing antibodies in mucosal secretions. The Applicant supports this argument by reference to the teachings of VanCott et al. (J Immunol, Vol. 160, pages 2000-12- of record in the IDS of February 2007). In particular, Table IV (page 2009) of this reference shows that a particular truncated gp160 protein (consisting, according to page 21, lines 28-30 of the present application, of residues 33-681 of SEQ ID NO: 1) expressed from a particular cell line infected with a particular strain of HIV induced a significantly greater mucosal immune response than another recombinantly expressed, full-length, gp160 similarly formulated. It is agreed that the teachings of this reference show unexpected results with respect to a formulation comprising that specific antigen.

However, the present claims are not limited to that antigen. Where an applicant argues that claims are non-obvious by reason of unexpected results, the evidence of such results must be commensurate in scope with the claims which the evidence is intended to support. See e.g., MPEP 716.02(d). In the present case, the evidence indicates that an antigen produced by a particular cell infected with a particular HIV was for some reasons able to induce a better

Art Unit: 1648

neutralizing mucosal immune response than other HIV gp160 antigens. The evidence does not show that truncated gp160 from any source, or that any gp160 antigen comprising, or consisting of the amino acid sequence of residues 33-681 of SEQ ID NO: 1 would induce the same results. For example, the teachings of the reference compare a recombinantly produced gp160 to the specific truncated form of gp160. It is not clear if the difference in the immune response is due to the truncation, to the mode of production and isolation of the protein, or of the sequence of the protein. As such, the teachings do not show that any truncated gp160, and truncated gp160 comprising the hydrophobic sequence of the truncated antigen of VanCott, or that any truncated gp160 consisting of residues 33-681 from any source, would be similarly effective in induce the more effective mucosal response. As such, the present claims are not commensurate in scope with the evidence of unexpected results. The argument is therefore not found persuasive with respect to the pending claims, and the rejection is therefore maintained.

6. **(Prior Rejection-Maintained)** Claims 19 and 21-35 were rejected under 35 U.S.C. 103(a) as being obvious over WO 95/11700 in view of the 292 patent, and further in view of U.S. 5,116,740 (the 740 patent). Applicant's arguments in traversal are not found persuasive for the reasons indicated above. The rejection is therefore maintained over pending claims 19, 21-23, 26-28, 30, and 35.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1648

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

8. **(Prior Rejection- Maintained)** Claims 19 and 21-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, and 8 of U.S. Patent No. 5,726,292 further in view of either of Anselem or WO 95/11700, and further in view of Vancott and Desai. Applicant's arguments in traversal are not found persuasive for the reasons indicated above. The rejection is therefore maintained over pending claims 19, 21-23, 26-28, 30, and 35.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1648

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. Lucas/
Patent Examiner, AU 1648